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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,573	06/04/2001	Gerard Alaux	SYL 501	9108

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EXAMINER
OH, SIMON J

ART UNIT	PAPER NUMBER
1615	6

DATE MAILED: 08/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,573	ALAUX ET AL.	
	Examiner	Art Unit	
	Simon J. Oh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-9,11,12 and 14-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-9,11,12 and 14-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-8, 12, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Penners *et al.* (U.S. Patent No. 5,651,985)

The Penners *et al.* patent teaches a pharmaceutical dosage form designed to have an extended gastric residence time in order to increase the amount of an active substance absorbed in the upper gastrointestinal tract (See Abstract; and Column 1, Lines 1-13 and 35-67). The dosage form comprises the active substance and customary pharmaceutical excipients, as well as a mixture of polymers containing lactam groups and polymers containing carboxyl groups. The dosage form may also optionally comprise a gas-generating component (See Column 3, Line 55 to Column 4, Line 3). Polyvinylpyrrolidone is given as an example of a polymer containing a lactam group. Carboxymethylcellulose and acrylic resins such as those sold under the trade name EUDRAGIT® are given as examples of polymers containing carboxyl groups (See

Column 4, Lines 4-31). The gas-generating component comprises agents which form non-toxic gases when introduced to water or gastric fluid. Such agents include sodium hydrogen carbonate, which may be employed alone or in combination with as acid, such as citric acid (See Column 5, Lines 11-21). The dosage form is preferably in an embodiment in which the active substance is kept in a separate layer from the mixture of polymers containing lactam groups and polymers containing carboxyl groups, such as in a dual-layer tablet (See Column 5, Lines 39-55; and Figures 2-4). Captopril is listed among those active substances that are particularly suitable for the disclosed dosage form (See Column 5, Lines 3-9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6-9, 11, 12, and 14-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penners *et al.* in view of Wong *et al.* (U.S. Patent No. 6,120,803), Shell (WIPO Document No. WO 97/47285), and Maggi *et al.* (WIPO Document No. 98/08515)

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The Penners *et al.* patent teaches a pharmaceutical dosage form designed to have an extended gastric residence time in order to increase the amount of an active substance absorbed in the upper gastrointestinal tract (See Abstract; and Column 1, Lines 1-13 and 35-67). The dosage form comprises the active substance and customary pharmaceutical excipients, as well as a mixture of polymers containing lactam groups and polymers containing carboxyl groups. The dosage form may also optionally comprise a gas-generating component (See Column 3, Line 55 to Column 4, Line 3). Polyvinylpyrrolidone is given as an example of a polymer containing a lactam group. Carboxymethylcellulose and acrylic resins such as those sold under the trade name EUDRAGIT® are given as examples of polymers containing carboxyl groups (See Column 4, Lines 4-31). The gas-generating component comprises agents which form non-toxic gases when introduced to water or gastric fluid. Such agents include sodium hydrogen carbonate, which may be employed alone or in combination with as acid, such as citric acid (See Column 5, Lines 11-21). The dosage form is preferably in an embodiment in which the active substance is kept in a separate layer from the mixture of polymers containing lactam groups and polymers containing carboxyl groups, such as in a dual-layer tablet (See Column 5, Lines 39-55; and Figures 2-4). Captopril is listed among those active substances that are particularly suitable for the disclosed dosage form (See Column 5, Lines 3-9).

The Penners *et al.* patent does not teach a gastric-retentive dosage form which further comprises a hydrophilic excipient capable of promoting polymer hydration, nor does it disclose lipid substances to be used in the dosage form. The patent does not specifically state that

benzamides, alpha-1 antagonists, or those active substances listed in Claim 27 can be used as the active ingredient in the disclosed dosage form.

The Wong *et al.* patent teaches a dosage form designed for retention in the stomach and prolonging the delivery of an active substance in that environment (See Abstract). The disclosed dosage form comprises water-soluble polymers, including polyvinylpyrrolidone, hydroxypropyl cellulose, hydroxypropylmethylcellulose, sodium carboxymethylcellulose, xanthan gum, and blends thereof (See Column 5, Line 55 to Column 6, Line 2). The dosage form also comprises hydroattractant polymeric excipients, such as microcrystalline cellulose, as well as other excipients, including mannitol, sorbitol, polaxamers, polysorbates, and effervescing couples, such as citric acid blended with sodium bicarbonate (See Column 6, Lines 3-31). The dosage form also comprises a band made from materials such as ethylcellulose, copolymers of acrylic acid and methacrylic acid, carnauba wax, white or yellow beeswax, castor wax, and mixtures thereof (See Column 13, Line 33 to Column 14, Line 6). Among the drugs suitable for this invention are captopril (See Column 18, Line 59), amoxicillin (See Column 19, Line 24), and prazosin hydrochloride (See Column 19, Line 65-66).

The Shell document discloses a dosage form designed to administer a drug at a sustained rate of release for an extended period of time in the stomach and upper intestinal tract, comprising of a water-swellable polymer matrix (See Abstract). The document also discloses those drugs that would benefit from such a delivery system, including captopril and metoclopramide (See Page 1, Lines 10-27; Page 7, Line 36; and Page 8, Line 29).

The Maggi *et al.* document discloses a dosage form for the controlled release of alfuzosin hydrochloride. The dosage form comprises of a layer that swells upon contact with aqueous

biological fluids, as well as a layer comprising the active ingredient in a hydrophilic polymer matrix. The dosage form is designed to release the drug at the proximal segments of the gastro-intestinal tract, namely the duodenum and the jejunum (See Abstract; and Page 1, Lines 19-23).

It would be obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Penners *et al.*, Wong *et al.*, Shell, and Maggi *et al.* into the objects of the instant application. Based on the similarities of their respective disclosures, one of ordinary skill would be motivated to combine the teachings of Penners *et al.* and Wong *et al.*, because as stated in *In re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA- 1980), "It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose." As this court explained in Crockett, 126 USPQ 186, 188 (CCPA- 1960), the idea of combining them flows logically from their having been individually taught in the prior art. Shell and Maggi *et al.* teach additional drug compounds that would benefit from the administration of a drug from a dosage form designed for a sustained rate of release over an extended period of time in the upper gastrointestinal tract, and thus one of ordinary skill in the art would be motivated to use alfuzosin hydrochloride and metoclopramide in a dosage form embodying the combined teachings of Penners *et al.* and Wong *et al.* with a reasonable expectation of success. Thus, the claimed invention as a whole is *prima facie* obvious.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Patent Examiner
AU 1615

sjo
August 22, 2002

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